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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,550	01/05/2004	Mona B. Damaj	017575.0775(TAMUS 1913)	2396
5073	7590	11/03/2005	EXAMINER	
BAKER BOTTS L.L.P. 2001 ROSS AVENUE SUITE 600 DALLAS, TX 75201-2980			BUI, PHUONG T	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/751,550	Applicant(s) DAMAJ ET AL.	
	Examiner Phuong T. Bui	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 17 and 37-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 57-61 is/are allowed.
- 6) ☒ Claim(s) 2-6, 17 and 37-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/29, 8/3, 9/6/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's amendment filed September 6, 2005. Claims 1-6, 17 and 37-61 are pending and are examined in the instant application. All previous rejections not set forth below have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. This action is made FINAL.

Claim Rejections - 35 USC § 112, first paragraph

2. Claims 2-6, 17, and 37-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:1, does not reasonably provide enablement for sequences having less than 100% sequence identity to SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is maintained for reasons of record.

Applicant traverses primarily that the level of skill of those in the art is high and the specification provides detailed descriptions of how to test for promoter activity.

Applicant's traversals have been considered but are deemed unpersuasive because while those skilled in the art can readily make mutations to SEQ ID NO:1 and test for promoter activity, further guidance is necessary as to what mutations would predictably and reliably yield sequences having promoter activity. The mutations include additions, deletions, substitutions and combinations thereof to any region of SEQ ID NO:1. At 60% sequence identity, the possible permutations involved are

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virtually *ad infinitum*. Applicant provided no guidance as to which region(s) of SEQ ID NO:1 should be conserved and which region(s) would tolerate mutations. Applicant provided no guidance as to how inoperable embodiments can be readily eliminated other than by random trial and error. Applicant provided no working example of a promoter sequence having 60-98% sequence identity to SEQ ID NO:1. Promoters do not have degeneracy codons or conservative substitutions like protein sequences. It is likely that a single base mutation would abrogate promoter activity. To require one skilled in the art to make all possible permutations and test each mutated sequence in an expression construct to determine whether or not it has promoter activity is not routine experimentation. Such experimentation would be excessive and undue.

Accordingly, this rejection is maintained.

3. Claims 2-6, 17, and 37-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This written description rejection is maintained for reasons of record.

Applicant traverses primarily that SEQ ID NO:1 would disclose a partial structure for each species and its functional characteristic is disclosed. Applicant cited *Capon v. Dudas*, Slip Opinion 03-1480-1481 (Fed. Cir., August 12, 2005).

Applicant's traversals have been considered but are unpersuasive for the following reasons. *Capon* is not on point because *Capon* is directed to a chimeric gene

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encoding the scFV domain and the transmembrane/cytoplasmic domains of an endogenous protein. *Capon* does not address whether the disclosure of a single sequence provides adequate written description for the genus of sequences having at least 60% sequence identity to SEQ ID NO:1. The instant claims are directed to promoter sequences obtained from sources other than the single sugarcane plant disclosed, whereby their structure and identity are not disclosed, so long as they share at least 60% sequence identity with SEQ ID NO:1. The claims encompass mutants and allelic variants of sugarcane and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. The disclosure of SEQ ID NO:1 isolated from sugarcane alone is not representative of other promoter sequences from other sources. Thus, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants and allelic variants of other sequences, or even other promoters, from another sugarcane plant, a plant other than sugarcane, or an organism, absent further guidance. This is precisely the situation in *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of the sequence encoding a rat insulin protein does not provide adequate written description for the sequence encoding a human insulin protein. Applicant failed to disclose a representative number of species within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Accordingly, there is lack of adequate

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description to inform a skilled artisan that Applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

Remarks

4. Claims 1 and 57-61 are allowable.
5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

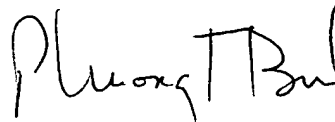
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Phuong T. Bui'.

Phuong T. Bui
Primary Examiner
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10/21/05